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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/439,040 11/12/99 VAN DONGEN

J 4222US

HM22/0521

EXAMINER

WILDER, C

ALLEN C TURNER
TRASK BRITT & ROSSA
P O BOX 2550
SALT LAKE CITY UT 84110

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/439,040

Applicant(s)

Van Dongen et al.

Examiner

CB Wilder

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 8, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-12 and 14-21
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☒ Other: Applicant's amendments do not overcome the prior art rejections for reasons discussed in the Attachment to the Advisory Action.

Interview Summary

Application No.
09/439,040

Applicant(s)
Van Dongen et al.

Examiner
CB Wilder

Group Art Unit
1655



All participants (applicant, applicant's representative, PTO personnel):

(1) CB Wilder

(3) _____

(2) Allen Turner For Applicant

(4) _____

Date of Interview May 18, 2001

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: _____

Identification of prior art discussed:

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

The Examiner telephoned Mr. Turner to inform him that Applicant's After-Final amendment has been recieved in the office and will be reviewed promptly.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

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ATTACHMENT TO ADVISORY ACTION

1. Applicant's amendment filed May 8, 2001 in Paper No. 13 is acknowledged. Claims 1-12 and 17-21 have been amended. Claims 1-12 and 14-21 are pending. Applicant's amendments do not overcome the prior art rejection for the reasons discussed below.

Priority

2. Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in European Patent Office EP 97201440.1 on 05/13/1997. The certified copy of the application has been provided in the instant application.

3. Applicant traverses the rejections on the following ground: Applicant argues that Tkachuk et al. provides a probe ("PEM12") that spans/overlaps the breakpoint cluster region. Applicant argues that a second probe is also provided by Tkachuk et al., separated from the first probe which spans/overlaps the breakpoint cluster by a distance of between 15-200 base pairs. Applicant states that these probes are in stark contrast to the presently claimed invention where probes are provided which lie adjacent to or flank the breakpoint cluster region and do not lie within or span or overlap the breakpoint cluster region. Applicant states that Applicants specifically disclose that false positive diagnosis may arise from the (a) the use of probes (such as the probes of Tkachuk) that overlap the breakpoint cluster region, and (b) the use of probes (such as probes of Tkachuk) directed against different chromosomes with juxtaposition of both signals into one signal in the case of translocation.

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Applicant argues that in contrast, the claimed invention provides a means to avoid such false positive diagnoses by using the claimed probes, i.e., ones lying adjacent to/ flanking, but not lying within the breakpoint cluster region on one chromosome giving rise to a split signal (i.e., two separate signals) after translocation.

Finally Applicant argues that the kits disclosed by Rowley et al. do not provide pairs of probes. Applicant states that the particular nucleic acid probes specified by Rowley et al. MLL 0.7B and MLL 0.3BE lie adjacent to one another and are smaller than 1KB. Applicant further states that the furthermore, MLL 0.7 lies with the breakpoint region. Applicant concludes that due to their small size, such probes could not be used in combination with MLL 1.5 EB for FISH detection purposes. Applicant states that accordingly, Rowley et al. cannot anticipate claim 16.

4. Applicant arguments have been fully considered but they are not found persuasive for the reasons that follows: First, the courts have established that "during patent examination the pending claims must be interpreted as broadly as their terms reasonable allow" *In re Zletz*, 893 f. 2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). In this case, the claims as recited are only limited to a pair of nucleic acid probes having comparable size and flanking a potential breakpoint region of a chromosome and wherein the probes are labeled with a different reporter molecule. These limitation are recited in the reference of Tkachuk et al.. According to Webster's Collegiate Dictionary, "flanking" can be defined as "to be situated on both sides of" or "to place something on each side of". Therefore, as noted in the prior Office actions, Tkachuk teach a pair of probes flanking (placed on both sides of) a breakpoint region (see prior Office Action, Paper No.11). Furthermore, the

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argument that Applicant's probes avoids false positives diagnoses is irrelevant because the features upon which Applicant relies (i.e. ones lying adjacent to but not lying within the breakpoint cluster region on one chromosome giving rise to a split signal after translocation) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant has not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or how the amendments avoid such reference. Accordingly, the prior art rejection under 35 U.S.C. 102(b) drawn to claims 1-12, 14, 15, and 17-21 as being anticipated by Tkachuk et al. is maintained.

With regards to claim 16, it is the Examiner's position that Rowley et al. meet all of the limitations of the claimed invention. As discussed in the prior Office actions, Rowley et al. teach wherein the kit comprises 1 or more than one distinct nucleic acid probes having comparable size as given by the sequence of the probes and in figures 1 and 2. Contrary to Applicant's arguments, Rowley teach wherein the probes are 0.3 KB to 1.5 KB (See prior office Action, Paper No. 11) which does encompass a probe larger than 1 KB. Likewise Rowley teach that the cloned DNA probes form both sides of a breakpoint region of a chromosome are used with FISH to detect translocation (see prior Office Action, Paper No. 11). Therefore, the argument that Rowley teach probes lying within a breakpoint region is irrelevant to the instant invention because such a limitation is not recited in the claims. With regards to Applicant's arguments that such small probes could not be used in combination with the larger probes for FISH detection purposes is also irrelevant to the instant

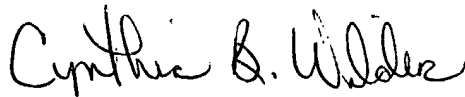
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invention because Applicant is arguing an intended use of a product (not a method step) which carries no patentable weight (see MPEP 2144.07). Applicant has not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or how the amendments avoid such reference. Accordingly, the prior art rejection under 35 U.S.C. 102(b) drawn to claim 16 as being anticipated by Rowley et al. is maintained.

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The Examiner can normally be reached on Monday through Thursday from 7:00 am to 5:00 pm.


If attempts to reach the Examiner by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.



Cynthia B. Wilder, Ph.D.

May 18, 2001



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600